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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,816	09/19/2003	Georges Rawadi	37991-0018	6623
26633	7590	01/20/2006	EXAMINER	
HELLER EHRMAN WHITE & MCAULIFFE LLP			PAK, JOHN D	
1717 RHODE ISLAND AVE, NW			ART UNIT	
WASHINGTON, DC 20036-3001			PAPER NUMBER	

1616

DATE MAILED: 01/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/665,816

Applicant(s)

RAWADI ET AL.

Examiner

JOHN PAK

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-12 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 6-7, drawn to method for preventing and/or treating a bone-related disease, wherein the administered GSK-3 $\beta$  inhibitor is lithium, classified in class 424, subclasses 677, 715, 722.
- II. Claim 6, drawn to method for preventing and/or treating a bone-related disease, wherein the administered GSK-3 $\beta$  inhibitor bivalent zinc, classified in class 424, subclasses 641, 643, class 514, subclass 494.
- III. Claim 6, drawn to method for preventing and/or treating a bone-related disease, wherein the administered GSK-3 $\beta$  inhibitor is beryllium, classified in class 424, subclasses 677, 722.
- IV. Claim 6, drawn to method for preventing and/or treating a bone-related disease, wherein the administered GSK-3 $\beta$  inhibitor is aloisines, classified in class 514, subclass 249.
- V. Claim 6, drawn to method for preventing and/or treating a bone-related disease, wherein the administered GSK-3 $\beta$  inhibitor is hymenialdisine, classified in class 514, subclass 212.06.
- VI. Claim 6, drawn to method for preventing and/or treating a bone-related disease, wherein the administered GSK-3 $\beta$  inhibitor is indirubins, classified in class 514, subclass 414.

- VII. Claim 6, drawn to method for preventing and/or treating a bone-related disease, wherein the administered GSK-3 $\beta$  inhibitor is maleimides, classified in class 514, subclass 425.
- VIII. Claim 6, drawn to method for preventing and/or treating a bone-related disease, wherein the administered GSK-3 $\beta$  inhibitor is muscarinic agonists, classified in multiple classes and subclasses depending on the chemical structure of the agonist, for example class 514, subclass 471 for muscarine, and class 514, subclass 397 for pilocarpine.
- IX. Claim 6, drawn to method for preventing and/or treating a bone-related disease, wherein the administered GSK-3 $\beta$  inhibitor is pyrazolo[3,4-b]quinoxaline, classified in class 514, subclass 249.
- X. Claim 6, drawn to method for preventing and/or treating a bone-related disease, wherein the administered GSK-3 $\beta$  inhibitor is 5-aryl-pyrazolo[3,4-b]pyridazines, classified in class 252.01+.
- XI. Claims 8-12, drawn to method for selecting a compound useful for preventing and/or treating a bone-related disease in a mammal, classified in class 424, subclasses 9.1+.

Claims 1-5 link inventions I to X. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 1-5. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions

shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The eleven inventions are distinct because they are each directed to the use of structurally distinct compounds (I to X) or a screening method (XI), which is independent from treatment methods. The structural divergence and distinctness are evident from the compound/substance categories of each of the inventions.

Further, most of the compound categories in each of the invention groups are separately classified, and even with respect to those that do share some classification overlap, a full and complete search and examination of the invention could hardly be limited to patent publications only given the medical applications of the claimed subject matter. The search would entail searching in databases for the specific compounds encompassed by each category of compounds or substances. There would already be serious burden on the Examiner in having to search just one invention group due to the

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breadth of "bone-related disease" such as those recited in claim 4, for example, so any additional burden represented by search and examination of additional invention group(s) would place an undue burden on the Examiner.

Therefore, for reasons of distinctness and undue burden, the restriction requirement as set forth above is deemed to be proper.

A telephone call was made to Ms. Granados on 1/17/2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620**. The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

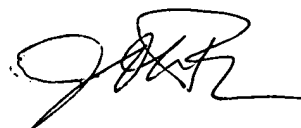
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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Gary Kunz, can be reached on **(571)272-0887**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JOHN PAK  
PRIMARY EXAMINER  
GROUP 1616